

Appl. No. : 10/771,845  
Filed : February 4, 2004

## REMARKS

By way of summary, Claims 1-7, 10-13, 15, 16, and 48-56 are pending in this application. In the outstanding Office Action of March 12, 2009, Claims 1-7, 10-13, 15, 16 and 48-56 were rejected under 35 U.S.C. §103(a) as unpatentable over Shaw (U.S. 6,080,182) and in further view of Peavey (U.S. Publ. 2003/0225421). Claim 10 has been amended.

### **I. Claim Amendments**

In this Amendment, Claim 10 has been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

### **II. §103(a) Claim Rejection to Shaw in view of Peavey**

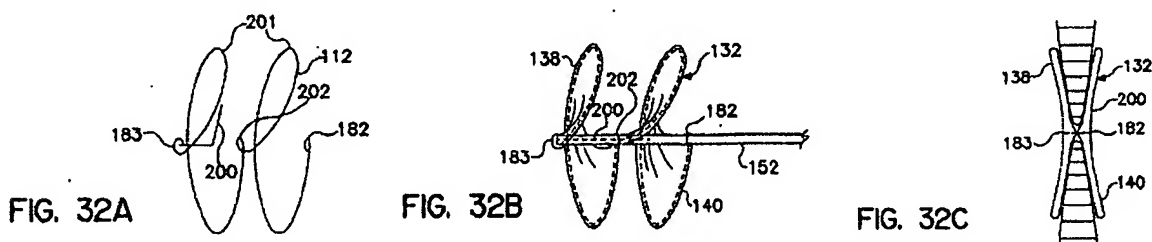
The Office Action of March 12, 2009 rejects Claims 1-7, 10-13, 15, 16 and 48-56 under 35 U.S.C. §103(a) as unpatentable over Shaw and in view of Peavey.

#### **A. Shaw is not properly combinable with Peavey**

The Office Action admits that Shaw "fails to specify the type of heart defect including a patent foramen ovale (PFO)" at page 5. The Office Action then makes a conclusory statement that "it would have been obvious to one of ordinary skill in the art to use the defect of Peavey with the device of Shaw as it is well known in the art that a PFO is a common defect as described in Peavey." Applicant respectfully disagrees with this conclusory statement, and rebuts the combination of Shaw and Peavey as improper, as it would require significant, non-obvious modifications to the Shaw device for it to work in a PFO, and one skilled in the art would have no reasonable expectation of success.

As disclosed in Applicant's specification, the PFO is different from a general septal defect, which tends to be a through hole in a wall: "In contrast to other septal defects which tend to have a generally longitudinal axis, a patent foramen ovale tends to behave like a flap valve.

Accordingly, the axis of the patent foramen ovale tends to be at an angle, and almost parallel to the septal wall.” Applicant specification at [0009]. Shaw does not mention any PFO, septum primum, septum secundum, or any flap structure or channel formed between flaps associated with its septal defects. Shaw is directed to occlude circular holes. Some of the figures in Shaw that are referenced in the Office Action include Figs. 7A-7C and Figs. 32A-32C. The cited Figures clearly show Shaw’s device used in open, through holes with no overlapping tissues or overlapping septa:



Shaw provides no disclosure, teaching or suggestion of how to make the significant modifications that would be necessary to modify, reconfigure and redesign the Shaw device to work in a PFO. Moreover, Applicant submits that that one skilled in the art would not find it predictable or have any reasonable expectation of success that that the device of Shaw could be used in a PFO tunnel. While Shaw may disclose a device for use in a hole, Shaw does not mention a PFO or any use of its device in the specialized structure of the PFO. Shaw’s device uses a wire helical under structure to spread out an occluder panel on each side of a circular hole in a septum. The PFO channel does not consist of a simple open circular hole in a tissue membrane—instead, the PFO channel is formed by overlapping atrial septa. One would not be motivated to place and use the devices of Shaw in a PFO because Shaw’s helical wire structure would separate the flaps of the PFO, prying open the overlapping tissue to allow more fluid flow between the atria, thereby frustrating the purpose of the Shaw device.

More particularly, Shaw’s design only contemplates a defect as a hole in the wall of a tissue (Shaw, col. 1, ll. 23-29). It is not obvious that the Shaw device, designed for use in open non-overlapping holes, can be used to close channels comprised of overlapping flaps that have different functional characteristics than those of holes. Applicant respectfully disagrees with the combination of Shaw with Peavey, as the teachings of Shaw do not lead to predicable results since the Shaw device is not configured to deploy in a PFO and cannot be modified to work in a

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PFO because the Shaw helical structure would interfere with the closure of the PFO's overlapping flaps.

Applicant respectfully disagrees with several of the Office Action's characterizations of Shaw. Claim 1 recites, in part, "deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in the channel between the overlapping septum primum and the septum secundum." At page 3, the Office Action characterizes Shaw with an "intermediate segment lying in a channel between the septum primum and the septum secundum" without noting any "overlapping" septum primum and the septum secundum, as recited in at least Claim 1. As discussed above, Shaw fails to disclose, teach or suggest "deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in the channel between the overlapping septum primum and the septum secundum" as claimed in independent Claim 1.

Amended Claim 10 recites, in part, "locking the closure device in its clip configuration after deployment with a locking element to increase the clamping force of the closure device on the septa of the patent foramen ovale, wherein the closure device when deployed exerts a force to draw the overlapping septum primum and septum secundum together." Shaw does not disclose, teach or suggest a "closure device when deployed exerts a force to draw the overlapping septum primum and septum secundum together." Shaw does not even contemplate channels formed by overlapping tissue. The device of Shaw can not properly be combined with the Peavey reference for application in a PFO.

**B. Even if combined, Shaw and Peavey fail to teach or suggest aspects of the Claims**

Claim 1 recites, in part, "a locking element that is separate from the proximal segment, intermediate segment and the distal segment." The Office Action characterizes Shaw's flexible inner tube 152 as a locking element that is "separate from the proximal segment, intermediate segment and the distal segment." Office Action at page 3. The Office Action indicates that once the flexible inner tube 152 is removed the Shaw "locking element" locks: "removal of 152 causes the element to lock, as the element has shape memory and automatically locks on to the tissue

after removal of element 152.” Office Action at page 3. The material comprising Shaw’s proximal segment, intermediate segment and the distal segment, as characterized by the Office Action (whether shape-memory or not), is an integral feature of the proximal segment, intermediate segment and the distal segment. The material of the proximal segment, intermediate segment and the distal segment is not “separate from the proximal segment, intermediate segment and the distal segment” thus the Office Action’s characterization of a shape-memory material lock does not satisfy this limitation in at least Claim 1.

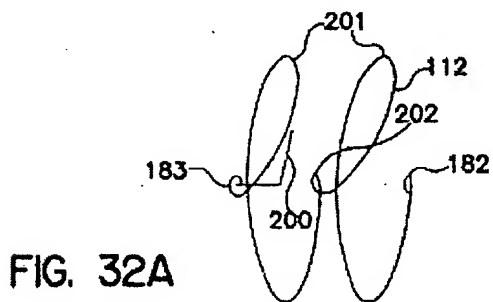


FIG. 32A

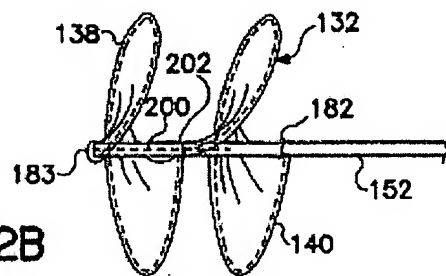


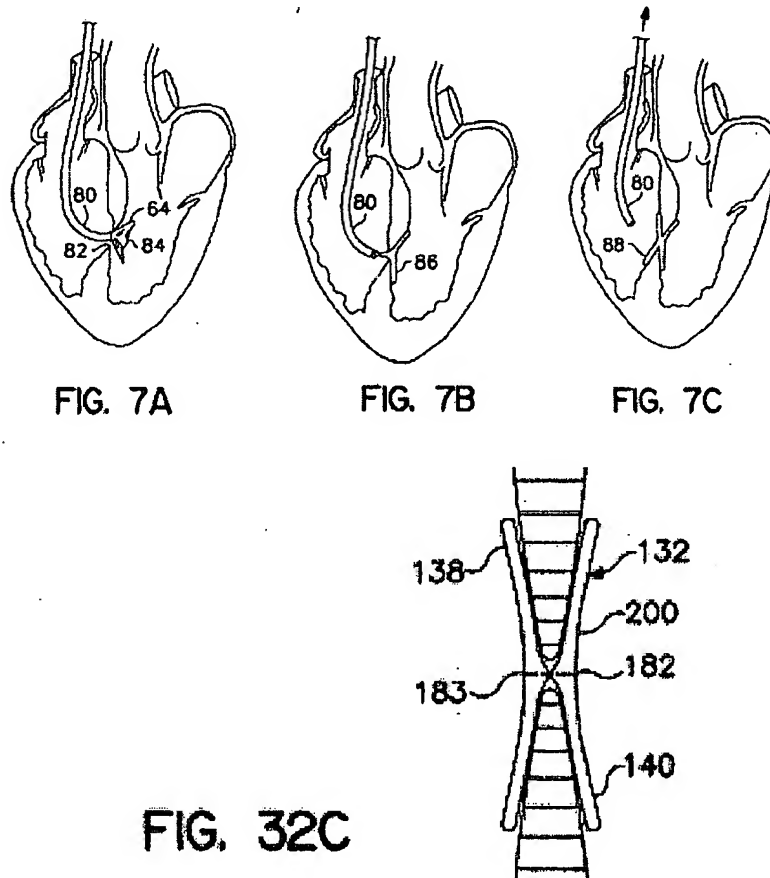
FIG. 32B

Furthermore, the latch 200 structure mentioned in Shaw col. 15, lines 5-37 can not be considered a locking element that is “separate from the proximal segment, intermediate segment and the distal segment” because Shaw’s latch 200 is integral with, and not separate from, the wire structure: “As shown in FIG. 32 (A), the helical wire 112 is formed into two loops or peripheries 201, a proximal eyelet 182, an intermediate eyelet 202, a distal eyelet 183 and a latch 200.” Shaw col. 15, lines 10-13. The latch 200 replaces the shape-memory aspects Shaw describes in another embodiment that are characterized as a “locking element” in the outstanding Office Action. Shaw states latch 200 is integrated into the helical wire:

Referring to FIGS. 23 (B) and 32 (A), the latch 150 and memory induced shape 162 have been replaced with the distal eyelet 183 and latch 200 respectively. Thus the sealing member securing and sealing member to sealing member securing means have been integrated into the helically formed wire. As shown in FIGS. 32 (B) and (C), the latch 200 passes through the three eyelets 182, 202, 183 and springs open to the unconstrained state when the inner tube 152 is withdrawn. The latch 200 thus acts as a sealing member securing and sealing member to sealing member securing means. The latch 200 can be formed into alternate shapes such as loops, coils and peripheries. Multiple latches can also be configured. Closure devices with single or multiple sealing members can also be configured.

Both Shaw's latch 200 and the shape memory material are not "separate from the proximal segment, intermediate segment and the distal segment."

Claim 1 recites, in part, "wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together." Amended Claim 10 recites, in part, "wherein the closure device when deployed exerts a force to draw the overlapping septum primum and septum secundum together." Page 3 of the Office Action argues that the Shaw "closure device when deployed exerts a force to draw the septum primum and septum secundum together (Figs. 7, 32C)." The septa in Figs. 7 and 32C are not overlapping, rather they are positioned one above the other as edges of a hole, as drawn in Shaw's figures. Some of the Shaw Figures referenced in the office action include:



In this orientation, the clamping force of the Shaw device cannot draw its septa closer together. The Shaw closure device when deployed exerts a force in a direction normal to the plane of the septa. Thus, Shaw's closure device may squeeze the edge on both sides of a planar hole septal defect, but it does not "draw the septum primum and septum secundum together" as recited in

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part in independent Claim 1, nor does it “draw the overlapping septum primum and septum secundum together” as recited in part in independent Claim 10.

Further, Claims 49 and 52 recite, in part, “wherein the locking element is provided as a retained part of the closure device after deployment.” Shaw states, “As shown in FIG. 22 (E), the flexible inner tube 152 can then be drawn away from the helical closure device 132, seating the latch 150 against the distal side 138 of the helical closure device 132.” Shaw col. 12, lines 15-19. Shaw’s locking element (flexible inner tube 152) is removed to lock the Shaw device, thereby it fails to be “a retained part of the closure device after deployment.” Furthermore, the Office Action at page 6 later admits that “Shaw ... does not teach a separate lock that remains in the body after deployment.” Thus, at least Claims 49 and 52 are not properly rejected under Shaw and in further view of Peavey.

Claims 55 and 56 recite, in part, “wherein the locking element remains within the patent foramen ovale after deployment.” Since Shaw’s locking element (flexible inner tube 152) is removed to lock the Shaw device as described above, it fails to remain “within the patent foramen ovale after deployment.” Thus, at least Claims 55 and 56 are not properly rejected under Shaw and in further view of Peavey.

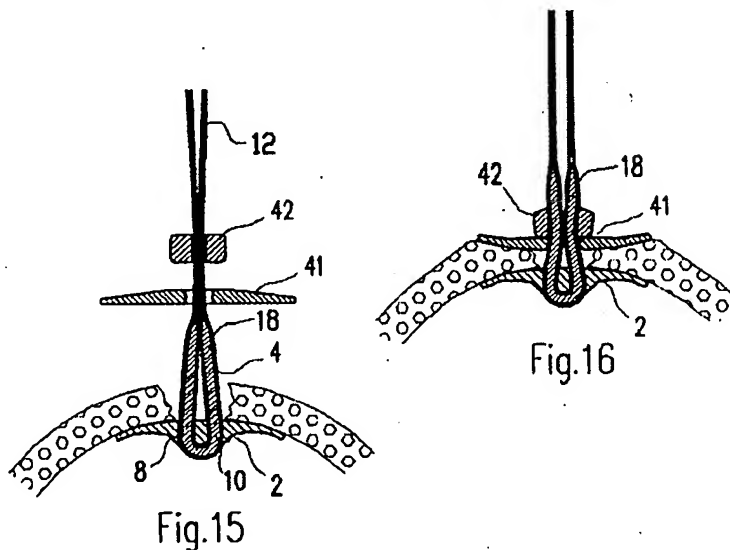
Accordingly, at least independent Claims 1 and 10 and their dependent claims are allowable over Shaw even if combined with Peavey. Peavey fails to correct or address the deficiencies of Shaw as described herein. For at least the foregoing reasons, Applicant respectfully submits that independent Claims 1 and 10 are not rendered obvious by Shaw even if combined with Peavey. The remaining rejected claims under Shaw in view of Peavey (2-7, 11-13, 15, 16 and 48-56) depend from one of independent Claims 1 and 10 and are allowable for the same reasons set forth above with respect to Claims 1 and 10 in addition to the patentable subject matter contained therein. Accordingly, withdrawal of the §103 rejections based on Shaw in view of Peavey regarding Claims 1-7, 10-13, 15, 16 and 48-56 is respectfully requested.

### **III. §103(a) Claim Rejection to Shaw in view of Peavey and Akerfeldt**

The Office Action of March 12, 2009 rejects Claims 1, 10, 49, 52, 55 and 56 under 35 U.S.C. § 103(a) as unpatentable over Shaw and in view of Peavey and Akerfeldt. Some of the deficiencies of Shaw and Peavey are described above. Akerfeldt fails to resolve the deficiencies

of Shaw and Peavey. Akerfeldt is directed to blood vessel wall wound closure. Blood vessels tend to be cylindrical in shape and do not tend to have overlapping flaps in the vessel walls.

At page 6 the Office Action admits that "Shaw ... does not teach a separate lock that remains in the body after deployment" then asserts that "Akerfeldt teaches a lock (42, Fig. 16) that is separate from the proximal, distal and intermediate segments, and remains within the body after deployment. Figure 16 from Akerfeldt is provided below:

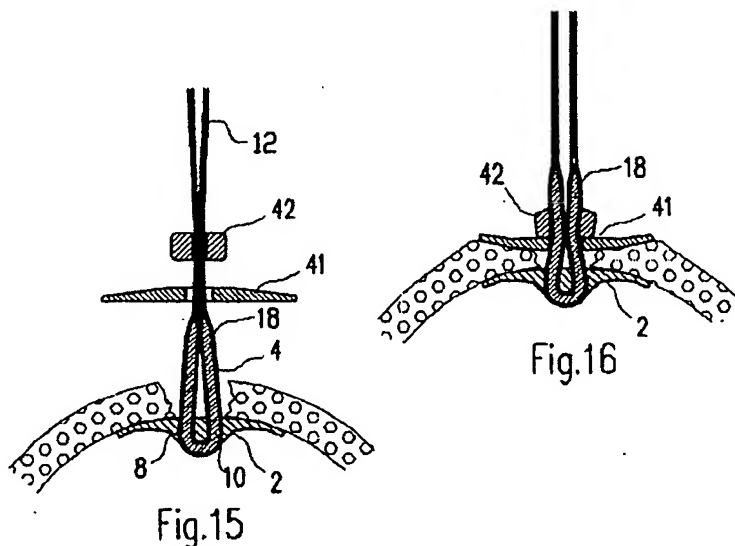


Akerfeldt's disclosure on reference 42 states:

In a fifth embodiment of the present invention, (FIGS. 15 and 16) **the second sealing member is divided into two parts, which first part 41 is a plate** and is provided with an opening that is approximately the same or slightly greater than the thickness of the distal lock portion 16. This first part 41 is threadable onto and along the elongate member 4 (FIG. 15), over the distal lock portion until it is in contact with the outside of the vessel wall. The first part plate 41 is preferably quite thin, which makes it flexible and easy to adapt to the vessel wall. **The second part 42** is provided with an opening that is slightly smaller than the thickness of the distal lock portion 16. This second part 42 is threadable onto and along the elongate member 4 (FIG. 15), over the distal lock portion until it is in contact with the first part 41. The second part 42 allows for frictional engagement between the inside of the opening of the second part 42 and the distal portion 16 (FIG. 16). The second part 42 is preferably thicker than the first part 41, which gives it a large surface inside its opening for said frictional engagement. On the other hand, the diameter of the second part 42 is preferably smaller than the first part 41.

It is not obvious to use the Office Action's characterized Akerfeldt "lock," or second part 42, in combination with the device of Shaw. As described above, Shaw's tube 152 is removed after the Shaw implant is deployed, so there is no 'elongate member' or other structure for second part 42 to interact with after the Shaw device is implanted. Alternatively, second part 42 might be applied onto Shaw's helical implant wire itself; however it is not apparent how such an application could effectively lock the Shaw implant after deployment. Squeezing a wire with the ring structure second part 42 identified in Akerfeldt does not result in locking any aspect of Shaw's described features. Accordingly, one skilled in the art would have no reasonable expectation of success in making the proposed combination of Shaw with Akerfeldt.

Further, the second part 42 is half of Akerfeldt's second sealing member. It works to hold a plate 41 against a simple hole. As described with respect to defects in Shaw in view of Peavey above, Akerfeldt still fails to address the deficiencies of the combination of Shaw and Peavey because the characterized "lock" 42 appears to work in squeezing opposite sides of a septum but does not exert "a force to draw the septum primum and septum secundum together," nor does it exert "a force to draw the overlapping septum primum and septum secundum together." Claim 1 recites, in part, "wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together." Amended Claim 10 recites, in part, "wherein the closure device when deployed exerts a force to draw the overlapping septum primum and septum secundum together." The tissue in Akerfeldt figures 15 and 16 are not overlapping, rather they are positioned side to side as edges of a hole:





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In this orientation, the clamping force of the Akerfeldt "lock" 42 cannot draw the tissue closer together. The Akerfeldt "lock" 42, when deployed exerts a force in a direction normal to the plane of the tissue wall. Thus, Akerfeldt "lock" 42 may squeeze the edge on one side of a planar hole shaped defect, but it does not "draw the septum primum and septum secundum together" as recited in part in independent Claim 1, nor does it "draw the overlapping septum primum and septum secundum together" as recited in part in independent Claim 10.

Accordingly, at least independent Claims 1 and 10 and their dependent claims are allowable over Shaw even if combined with Peavey and Akerfeldt. Akerfeldt fails to correct or address the deficiencies of Shaw and Peavey as described herein. For at least the foregoing reasons, Applicant respectfully submits that independent Claims 1 and 10 are not rendered obvious by Shaw even if combined with Peavey and Akerfeldt. The remaining rejected claims under Shaw in view of Peavey and Akerfeldt (49, 52, 55 and 56) depend from one of independent Claims 1 and 10 and are allowable for the same reasons set forth above with respect to Claims 1 and 10 in addition to the patentable subject matter contained therein. Accordingly, withdrawal of the §103 rejections based on Shaw in view of Peavey regarding Claims 1, 10, 49, 52, 55 and 56 is respectfully requested.

#### **IV. No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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**V. Co-Pending Applications of Assignee**

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed	Matter Reference
11/607237	TISSUE OPENING OCCLUDER	11/30/2006	EV3.062DV2
11/927448	TISSUE OPENING OCCLUDER	10/29/2007	EV3.062C1
10/419412	SEPTAL DEFECT OCCLUDER	4/21/2003	EV3.058CPC1
12/356506	DEFECT OCCLUDER RELEASE ASSEMBLY & METHOD	1/20/09	EV3.059C2
12/110186	RETRIEVABLE SEPTAL DEFECT CLOSURE DEVICE	4/25/2008	EV3.067C1C1
10/972635	PATENT FORAMEN OVALE CLOSURE SYSTEM	10/25/2004	EV3.079A
10/783783	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE WITH A COIL-SHAPED CLOSURE DEVICE	2/20/2004	MVMDINC.060A
10/841880	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE USING A COUNTERTRACTION ELEMENT	5/7/2004	MVMDINC.068A

**VI. Conclusion**

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, the Examiner is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

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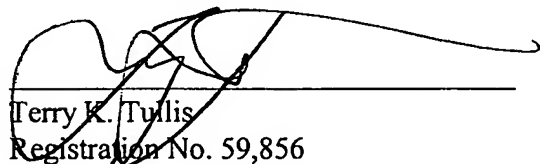
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 6-10-09

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